

Do Not Disclose - Subject to Further Confidentiality Review

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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

No. MD-15-02641-PHX-DGC

IN RE BARD IVC FILTERS PRODUCTS

LIABILITY LITIGATION

DO NOT DISCLOSE

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF CLEMENT J. GRASSI, MD

Thursday, June 15, 2017

9:24 a.m.

Held At:

Nelson Mullins Riley & Scarborough LLP

One Post Office Square

Boston, Massachusetts

REPORTED BY:

Maureen O'Connor Pollard, RMR, CLR, CSR

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21 Videographer: Christopher Coughlin

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1 the Recovery filter has experienced fractures,
2 why the G2 has experienced fractures, why the
3 Denali has experienced fractures.

4 A. I see. So if I understand correct,
5 you're asking me do I know of what Bard is doing
6 on this subject.

7 Q. Right. I asked you, for example, what
8 is -- what are the mechanisms to explain why the
9 filters fracture. You gave me an answer of
10 several mechanisms that have been described in
11 the literature, and you said one of them was
12 metal fatigue from stress, from the repetitive
13 changes, cycling of the vena cava. That was
14 one, right?

15 A. Yes.

16 Q. And then there were several others
17 that you gave in your answer.

18 My question is, do you know what
19 steps, if any, Bard has taken to determine the
20 answer to that question, what is causing the
21 filters to fracture?

22 A. No, I do not know what steps within
23 the company internally or via its consultants
24 Bard has worked on in that regard.

1 Q. And you have not asked that question
2 either? You have not asked Bard "what have you
3 done to figure this out"?

4 A. I have not personally asked. I have
5 an interest in the subject of vena cava filters,
6 and so in answer to your question, I'm aware of
7 what some of its more recent physician
8 investigators have done in regard to the newer
9 filter version, such as Dr. William
10 Stavrouopoulos with the Denali filter.

11 But in specific answer to your
12 question, no, I have not personally asked Bard
13 workers what they've done.

14 Q. And with respect to the first
15 mechanism that you described, which is the
16 fatigue from high cycle stress -- did I
17 accurately identify that mechanism?

18 A. That's fair.

19 Q. -- what evidence are you aware of in
20 the medical literature that supports that
21 mechanism as explaining fractures?

22 A. Well, I'm aware of what's been
23 commented on in the published literature, not
24 only for Bard devices, but all filters. I'm

1 aware of the testing that goes on by different
2 manufacturers on the benchtop and through
3 repetitive stress testing. I know from personal
4 experience when I participated in the Simon
5 nitinol FDA pre-approval testing what was done
6 in terms of testing with that filter device.

7 And so in specific answer to your
8 question, I'm aware in general of what's
9 reported publicly and data that's publicly
10 available.

11 Q. What is that evidence? What is the
12 evidence that the fractures -- the mechanism to
13 explain the fractures is high cycle fatigue of
14 the metal?

15 A. Well, the engineer designers or
16 metallurgists, and I'm neither of those, tell me
17 that in terms of the metal itself, that when the
18 number of repetitions goes up into the hundreds
19 of thousands of times, that there is the
20 potential for the metal not staying the same as
21 a new pristine filter. That's one body of
22 evidence.

23 Q. Stop there for a second.

24 Do you agree that there are hundreds

1 number of breaths and the number of cycles per
2 day that they quoted as their estimation of
3 standards.

4 Q. And you believe it's reasonable, the
5 discussion in that section, about the need for
6 an IVC filter to have the durability to last ten
7 years if it has an indication to be a permanent
8 filter?

9 A. In general, I agree that durability of
10 vena cava filter devices and longevity is
11 important.

12 Q. And you have not been provided with
13 anything from the lawyers or from Bard that
14 would show you how Bard and whether Bard did any
15 kind of testing to determine whether any of its
16 retrievable filters could meet that durability
17 standard?

18 MR. BROWN: Object to the form.

19 A. Well, in answer to that question, I am
20 aware of the processes and the standards that
21 the company C.R. Bard is required to undergo as
22 part of its FDA pre-acceptance testing under
23 what would be a 510(k) application. That
24 includes, and I believe I'm correct on this,

1 benchtop testing and stress testing of the
2 device over many hundreds of thousands of
3 cycles. However, I have not been provided the
4 specific documents on that topic.

5 BY MR. ROTMAN:

6 Q. Nor have you been provided with the
7 results of those tests?

8 A. That's correct.

9 Q. So you don't know how those tests --
10 what those tests show about the durability of
11 the Bard retrievable filters as compared to
12 their predicate devices?

13 A. Well, I may not have received the
14 multiple individual reports, but I would, of
15 course, rely on the FDA since it is the body
16 which approves the device. And since the device
17 was approved by the US FDA for clinical use,
18 then I would only have to assume that they met
19 or exceeded those benchmarks.

20 Q. Were you ever retained by Bard to
21 consult when it was dealing with a crisis that
22 involved a safety or a design issue with its
23 retrievable filters?

24 MR. BROWN: Object to the form.